

Docket No.: 337922US59SD

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: : EXAMINER: SHIAO, R.T.  
TAKANORI YASUKOUCHI, ET AL : GROUP ART UNIT: 1626  
SERIAL NO.: 10/500,156 : U.S. PATENT NO.: 7,399,775  
FILED: JUNE 25, 2004 : ISSUED: JULY 15, 2008  
FOR: BETA-AMYLOID PROTEIN PRODUCTION, SECRETION INHIBITOR

PETITION UNDER 37 C.F.R. §1.705(d) AND  
REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

COMMISSIONER FOR PATENTS  
P.O. BOX 1450  
ALEXANDRIA, VA 22313-1450

SIR:

Petitioners hereby request reconsideration of the final patent term adjustment for U.S. Patent No. 7,399,775 ("the '775 patent") of 293 days and, in place thereof, Petitioners request that the patent term adjustment be changed to 664 days.

Petitioners contend that the Office erred in determining patent term adjustment published on the face of the '775 patent by not properly accounting for the period of time where issuance of the '775 patent was delayed beyond three years of pendency (35 U.S.C. §154(b)(1)(B)).

Correction of the foregoing error in the patent term adjustment is requested in view of the present Petition including the facts and remarks that follow:

Patent Term Adjustment indicated in the Notice of Allowance and on the ‘775 Patent:

On February 4, 2008, a Notice of Allowance was issued in U.S. Application Serial No. 10/500,156, which indicated that the determination of patent term adjustment under 35 U.S.C. §154(b) was 296 days. This patent term adjustment represents the 370-day period in which the Office failed to mail of either an action under 35 U.S.C. §132, or a notice of allowance under 35 U.S.C. §151 following expiration of 14 months from filing (37 C.F.R. §1.703(a)(1)) from which a 62-day period and a 12-day period were subtracted which the Office considers as being a “failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application”.

On July 15, 2008, the Office issued U.S. 7,399,775. On the face of the ‘775 patent a patent term adjustment of 293 days is indicated. The difference between the number of days of patent term adjustment appearing on the Notice of Allowance and the number of days of patent term adjustment appearing on the face of the patent account for a 16-day period that the Office provided under the 3-year pendency guarantee from which a 1-day period (Payment of Issue Fee) and an 18-day period (Amendment under 37 C.F.R §1.312) were subtracted during which the Office considers as being a “failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application”.

Statute relevant to decision on Petition:

35 U.S.C. §154(b) provides for the patent term guarantees giving rise to an adjustment in patent term.

Specifically, 35 U.S.C. §154(b)(1) provides for the following adjustments to the patent term:

(1) PATENT TERM GUARANTEES.-

(A) GUARANTEE OF PROMPT PATENT AND TRADEMARK OFFICE

RESPONSES.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

(iii) act on an application within 4 months after the date of a decision by the Board of Patent Appeals and Interferences under section 134 or 135 or a decision by a Federal court under section 141, 145, or 146 in a case in which allowable claims remain in the application; or

(iv) issue a patent within 4 months after the date on which the issue fee was paid under section 151 and all outstanding requirements were satisfied, the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

(B) GUARANTEE OF NO MORE THAN 3-YEAR APPLICATION

PENDENCY.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Board of Patent Appeals and Interferences or by a Federal court; or

- (iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C), the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

(C) GUARANTEE OR ADJUSTMENTS FOR DELAYS DUE TO INTERFERENCES, SECRECY ORDERS, AND APPEALS.- Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to-

- (i) a proceeding under section 135(a);
- (ii) the imposition of an order under section 181; or
- (iii) appellate review by the Board of Patent Appeals and Interferences or by a Federal court in a case in which the patent was issued under a decision in the review reversing an adverse determination of patentability, the term of the patent shall be extended 1 day for each day of the pendency of the proceeding, order, or review, as the case may be.

Countering this period is the limitations enunciated in 35 U.S.C. §154(b)(2), which sets forth:

(2) LIMITATIONS.-

(A) IN GENERAL.- To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

(B) DISCLAIMED TERM.- No patent the term of which has been disclaimed beyond a specified date may be adjusted under this section beyond the expiration date specified in the disclaimer.

(C) REDUCTION OF PERIOD OF ADJUSTMENT.-

- (i) The period of adjustment of the term of a patent under paragraph (1) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application.
- (ii) With respect to adjustments to patent term made under the authority of paragraph (1)(B), an applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of 3 months that are taken to respond to

a notice from the Office making any rejection, objection, argument, or other request, measuring such 3-month period from the date the notice was given or mailed to the applicant.

- (iii) The Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application.

Grounds for Request for Reconsideration and Reinstatement of Patent Term Adjustment:

At issue in this case is the Office's misapplication of the provision in 35 U.S.C. §154(b)(2) that states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

On the face of the '775 patent a patent term adjustment of 293 days is indicated. The Office determination of the 293-day patent term adjustment is in error in that, pursuant to 35 U.S.C. § 154(b)(1)(B), the Office failed to properly allow an adjustment for the time exceeding three years after the actual filing date of the present application (June 25, 2007) to the date when the '775 patent issued (July 15, 2008). The correct patent term adjustment for the '775 patent is 664 days.

In this case, the period of patent term adjustment under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B) are calculated independently. The following is a summary of the time periods and the number of days of PTA:

*35 U.S.C. §154(b)(1)(A)*

**Plus 370 days** from August 25, 2005 (i.e., 14 months from the filing date of June 25, 2004) to August 30, 2006 when Office mailed a Restriction Requirement (i.e., an action under 35 U.S.C. §132) (35 U.S.C. §154(b)(1)(A)(i) and 37 C.F.R. §1.703(a)(1)).

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(A) = **370 days**.

*35 U.S.C. §154(b)(1)(B)*

**Plus 386 days** from June 25, 2007 (i.e., 3 years from the filing date of June 25, 2004) to July 15, 2008 when the present application issued as the ‘775 patent. No RCE was filed. Note: the Office’s calculated patent term adjustment on the face of the patent accounted for 16 days of this 386 day period.

TOTAL patent term adjustment under 35 U.S.C. §154(b)(1)(B) = **386 days**.

*35 U.S.C. §154(b)(2)(C) correction*

- 1) **Minus 62 days** due to Petitioners’ alleged failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the period of May 1, 2007 to July 2, 2007.
- 2) **Minus 12 days** due to Petitioners’ failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the period of November 31, 2007 to December 12, 2007.

- 3) **Minus 1 day** due to Petitioners' alleged failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the period of May 5, 2008 to May 6, 2008.

Note: This patent term adjustment reduction is in error as May 5, 2008 was a Sunday, thus the payment of the Issue Fee on May 6, 2008, was timely.

***Review and correction of this error is requested.***

- 4) **Minus 18 days** due to Petitioners' failure to engage in reasonable efforts to conclude prosecution of the application (35 U.S.C. §154(b)(2)(C) and 37 C.F.R. §1.704(a)) for the period of May 2, 2008 to May 19, 2008 (Amendment under 37 C.F.R. §1.312).

TOTAL correction to patent term adjustment under 35 U.S.C. §154(b)(2)(C) = **92 days** (the one-day reduction in (3) should be eliminated).

35 U.S.C. §154(b)(2) states "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith**, the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b).

Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that "[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day" (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

With this proper frame of reference, Petitioners return to the calculation above. There is no overlap between the A-delay and the B-delay for the '775 patent.

The resulting calculation of the patent term adjustment for the '775 patent should be as follows:

A delay		B delay		35 U.S.C. §154(b)(2) correction		Applicant Delay		Total PTA
370	+	386	-	92	-	0	=	664

In view of the foregoing and supported by *Wyeth v. Dudas*, Petitioners respectfully request that the Office correct the error in the patent term adjustment for the '775 patent and properly indicate that the patent term adjustment has been changed to 664 days.

In accordance with the provisions of 37 C.F.R. §1.704(b) and (d), Petitioners submit herewith the requisite fee under 37 C.F.R. §1.18(e). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).



For the foregoing reasons, Petitioners respectfully submit that the Request for Reconsideration of the Patent Term Adjustment of U.S. 7,399,775 should be GRANTED and the patent term adjustment should properly be indicated as 664 days. Early notification of such action is earnestly solicited.

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Respectfully submitted,

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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: : EXAMINER: SHIAO, R.T.  
TAKANORI YASUKOUCHI, ET AL : GROUP ART UNIT: 1626  
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PETITION UNDER 37 C.F.R. §1.183

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SIR:

Petitioners hereby request that the Director suspend the rules and consider their Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment **submitted herewith.**

When the patent term adjustment finally calculated by the Office is incorrect, patentees have two mechanisms by which to challenge the patent term adjustment. These two mechanisms are:

- 1) 37 CFR §1.705(d) - (e) relate to Requests for Reconsideration of the USPTO-determined patent term adjustment. 37 CFR §1.705(d) - (e) are reproduced below (*with emphasis added*):

(d) If there is a revision to the patent term adjustment indicated in the notice of allowance, the patent will indicate the revised patent term adjustment. If the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed ***within two months of the date the patent issued*** and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Any request for reconsideration

under this section that raises issues that were raised, or could have been raised, in an application for patent term adjustment under paragraph (b) of this section shall be dismissed as untimely as to those issues.

(e) The periods set forth in this section are ***not extendable***.

- 2) 35 U.S.C. §154(b)(4)(A) permits a challenge the USPTO calculated patent term adjustment by a civil action against the Director at the District Court for the District of Columbia within 180 days of patent grant.

The above-identified application published as U.S. 7,399,775 on July 15, 2008. On September 30, 2008, the District Court for the District of Columbia issued a decision related to the calculation of patent term adjustment - In *Wyeth v. Dudas*, Civil Action No. 07-1492 (JR) (2008 U.S. Dist. Lexis 76063 (D.D.C., September 30, 2008), copy **enclosed herewith**. In *Wyeth*, the Court issued an opinion explaining the proper method for calculating patent term adjustments under 35 U.S.C. § 154(b). Specifically, when determining the overlap defined in 35 U.S.C. §154(b)(2), the *Wyeth* Court held that “[t]he only way that [A and B] periods of time can 'overlap' is if they occur on the same day” (see page 3, left column, first fully paragraph). In other words, the A delay (i.e., delay under 35 U.S.C. §154(b)(1)(A)) and B delay (i.e., delay under 35 U.S.C. §154(b)(1)(B)) only overlap if the A delay occurs after three years of pendency.

The *Wyeth* decision has direct relevance to the above-identified patent as the Office has improperly calculated the patent term adjustment for the above-identified patent. As set forth in the Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment, submitted herewith, under *Wyeth* the above-identified patent should be entitled to an additional **370 days** of patent term adjustment resulting in a total patent term adjustment of **663** days.

37 C.F.R. §1.183 provides:

In an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes may be suspended or waived by the Director or the Director's designee, *sua sponte*, or on petition of the interested party, subject to such other requirements as may be imposed.

Although *Wyeth* is controlling of the issue in this case and, as such, is directly applicable to the case at hand, the applicability of this decision to the above-identified patent was not appreciated by Petitioners until after the passage of two-months from patent issuance. Accordingly, there is no possible regulatory relief specifically available to Petitioners despite the Office's error in calculating the patent term adjustment for the present application. Thus, this case represents an extraordinary situation where justice requires remedial action.

Petitioners submit that whereas the 180-day limit to file a civil action against the Director at the District Court for the District of Columbia is statutory, the 2-month non-extendible period for filing a Request for Reconsideration does not appear in the statute, but rather is only presented in the regulations. Thus, the Office is requested, and justice requires, to waive the 2-month non-extendible limit appearing in the regulations and permit Petitioners the opportunity to have their Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment properly decided.

In accordance with the provisions of 37 C.F.R. §1.183, Petitioners submit herewith the requisite fee under 37 C.F.R. §1.17(f). In the event that the Office determines that additional fees are required, it is requested that any underpayment be charged to their undersigned Representative's deposit account (Deposit Account No. 15-0030).

For the foregoing reasons, Petitioners respectfully submit that the Request for Suspension of the Rules should be GRANTED and the Petition Under 37 C.F.R. §1.705(d) and Request for Reconsideration of Patent Term Adjustment submitted herewith should be entered and favorably reviewed. Early notification of such action is earnestly solicited.

Respectfully submitted,

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